

- 13/11/2014
- (a) a compressed tablet comprising granulated ibuprofen and a carrier material consisting essentially of either maize starch at 35-38% total tablet weight in combination with dried maize starch at 3-4% total tablet weight or microcrystalline cellulose at 10-11% total tablet weight in combination with croscarmellose sodium at 14-16% total tablet weight and pre-gelled starch at 10% total tablet weight;
- (b) a direct compression tablet comprising a carrier material consisting essentially of microcrystalline cellulose at 8-11% total tablet weight and lactose at 5-6% total tablet weight;
- (c) a hard gelatin capsule comprising a carrier consisting essentially of maize starch at 15-20% total capsule contents weight in combination with pre-gelled starch at 5-6% total capsule contents weight.

2 26. A composition according to claim 25 characterised by comprising a granulating agent present to an extent of up to 10% of total tablet weight.

3 27. A composition according to claim 25 comprising a granulating agent consisting essentially of one or more of the following:
polymeric granulating agents selected from natural gums, synthetic gums and cellulose materials; a sugar granulating agent; a starch granulating agent.

Self
B2

28.

A composition according to claim 27 characterised in that the granulating agent is hydroxypropyl cellulose or hydroxypropyl methylcellulose.

6-29.

29.

A composition as claimed in claim ~~25~~ in the form of a directly compressed tablet composition comprising

- (i) an ibuprofen medicament;
- (ii) a domperidone medicament; and
- (iii) a carrier material,

characterised in that the carrier material is substantially free of povidone and comprises at least one diluent combined with at least one disintegrating agent and a lubricating agent.

FOR THE RECORD

Sub
C1

30.

A composition according to claim 25 comprising 20-60% carrier material including up to 15% of a discrete disintegrant material.

8-31.

31.

A composition according to claim ~~25~~¹ wherein the carrier material consists essentially of one or more of the following diluents: microcrystalline cellulose, tricalcium phosphate and lactose.

Sub
C2

32.

A composition according to claim 25 comprising one or more discrete disintegrants including croscarmellose sodium and sodium starch glycolate.

SWY
B3

33.

A composition according to claim 25 in which the ibuprofen medicament is racemic ibuprofen or S(+)-ibuprofen or the 8 sodium or lysine salts thereof, present to an extent of 50-65% by weight of the composition and the domperidone medicament is domperidone or the maleate salt thereof, present to an extent of 1-5% of the composition.

11 34.

A process to prepare a compressed composition according to claim 25 comprising (a) granulating said ibuprofen medicament, optionally with said domperidone medicament, with at least a first portion of said carrier material and a granulating fluid; (b) drying said granules; (c) blending with a lubricating agent and optionally a flow aid to form a homogeneous mixture, and (d) compressing into tablets.

12 35.

A process according to claim 34 further comprising a cellulose material as a granulating agent.

13 36.

A method of treating migraine which comprises the administration to a patient in need thereof a stable pharmaceutical composition according to claim 25.

14 37.

A composition as claimed in claim 25 in the form of a compressed tablet wherein the carrier material comprising a compressed mixture of